PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 01307-0010P1	FOR FURTHER ACTION	See item 4 below		
International application No. PCT/US2009/065764	International filing date (day/month/year) 24 November 2009 (24.11.2009)	Priority date (day/month/year) 24 November 2008 (24.11.2008)		
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237				
Applicant ACRYMED, INC.				

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis.</i> 1(a).				
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.				
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.				
3.	This report contains indications relating to the following items:				
	\mathbf{X}	Box No. I	Basis of the report		
		Box No. II	Priority		
		Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability		
		Box No. IV	Lack of unity of invention		
	\boxtimes	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
		Box No. VI	Certain documents cited		
		Box No. VII	Certain defects in the international application		
		Box No. VIII	Certain observations on the international application		
4.	but not,		communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 icant makes an express request under Article 23(2), before the expiration of 30 months from 2).		

	Date of issuance of this report 24 May 2011 (24.05.2011)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Simin Baharlou
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY To: WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International filing date (day/month/year) Priority date (day/month/year) International application No. 24.11.2009 24.11.2008 PCT/US2009/065764 International Patent Classification (IPC) or both national classification and IPC INV. A61F13/02 A61L15/00 Applicant ACRYMED, INC. This opinion contains indications relating to the following items: ☑ Box No. I Basis of the opinion ☐ Box No. II Priority Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. III ☐ Box No. IV Lack of unity of invention Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial Box No. V applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application **FURTHER ACTION** If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. 3. Name and mailing address of the ISA: Date of completion of **Authorized Officer** this opinion European Patent Office see form Beins, Ulrika

PCT/ISA/210

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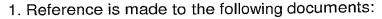
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2009/065764

	Box No. I Basis of the opinion				
	With regard to the language, this opinion has been established on the basis of:				
	a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).				
2.	☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))				
3.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:				
	a. (means)				
	□ on paper				
	☐ in electronic form				
	b. (time)				
	\square in the international application as filed				
	☐ together with the international application in electronic form				
	□ subsequently to this Authority for the purposes of search				
4.	☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.				
5.	Additional comments:				
	Box No. V Reasoned statement under Rule 43 <i>bis</i> .1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
1.	Statement				
	Novelty (N) Yes: Claims 15, 16, 30, 32-36 No: Claims 1-14, 17-29, 31, 37				
٠	Inventive step (IS) Yes: Claims 15, 16, 30, 32-36 No: Claims 1-14, 17-29, 31, 37				
	Industrial applicability (IA) Yes: Claims No: Claims				
2.	Citations and explanations				

see separate sheet



- D1 US 5 833 665 A (BOOTMAN MATTHEW [US] ET AL) 10 November 1998 (1998-11-10)
- DE 196 31 421 A1 (BEIERSDORF AG [DE]) 12 February 1998 (1998-02-12)
- D3 US 5 908 693 A (DELGADO JOAQUIN [US] ET AL) 1 June 1999 (1999-06-01)
- D4 US 2004/082925 A1 (PATEL HARISH A [US]) 29 April 2004 (2004-04-29)
- D5 US 7 189 410 B1 (DROHAN WILLIAM N [US] ET AL) 13 March 2007 (2007-03-13)
- D6 WO 2007/127236 A2 (ACRYMED INC [US]; MCMAKEN JACK D [US]; GIBBINS BRUCE L [US]) 8 November 2007 (2007-11-08)
- D7 US 5 407 685 A (MALCHESKY PAUL S [US] ET AL) 18 April 1995 (1995-04-18)
- D8 US 5 695 777 A (DONOVAN MAURA G [US] ET AL) 9 December 1997 (1997-12-09)
- 2. The application does not meet the requirements of Article 6 PCT, because the claims are not clear.
- 2.1 It is not clear what is meant with "binder". Is it a binder to bind the antimicrobial agent or is it an adhesive?
- 2.2 From the whole description and examples it is clear that the second layer is an adhesive layer. Therefore, claim 1 should be restricted to an adhesive layer. This is also necessary, since the independent method claim 22 refers to an adhesive and the independent claims should be consistent.
- 2.3 The term "substantially" in the claims is not clear and should be deleted.
- 2.4 Terms like "optionally" do not provide any limitation to the claims.
- 3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

3.1 Concerning independent claim 1, D1 discloses:

A laminate construct comprising at least one antimicrobial layer comprising at least one antimicrobial agent and a binder, and a second layer (column 1, line 65 - column 2, line 60).

D2 (column 1, lines 3-5; column 2, lines 20-36; column 3, lines 14-33), D3 (column 2, lines 41-50; column 3, lines 18-25; column 3, lines 59-65; column 8, lines 30-64; column 9, lines 8-17; column 9, lines 44-54), D4 (page 3, paragraph 31-39; page 4, paragraph 44-51), D5 (claims 1,5,8-11,17,18), D6 (pages 2,5-10), D7 (claims 1-9,13,21,22) and D8 (column 4, lines 56-63; claims 1,3,4) also disclose the subject-matter of claim 1.

3.2 Concerning independent claim 22, D1 discloses:

A method of making a laminate construct comprising,

- a. Applying an antimicrobial composition to a structural element to form a coating on the structural element (col. 6, l. 13-36);
- b. Removing at least a portion of one or more solvents from the antimicrobial composition to form an antimicrobial layer (col. 6, I. 13-36);
- c. Applying an adhesive composition to the outer surface of the antimicrobial layer (col. 6, l. 13-36);
- d. Removing at least a portion of one or more solvents from the adhesive composition to form an adhesive layer (col. 6, I. 13-36); and
- e. Optionally, adding a second structural element to cover the adhesive layer (see point 2.4 above).
- 3.3 Concerning independent claim 37, D1 discloses:

An article comprising a laminate construct of Claim 1 (column 1, line 65 - column 2, line 60).

- 4. Dependent claims 2-14,17-21,23-29,31 does not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
- D1 (column 1, line 65 column 2, line 60; column 3, lines 40-54; column 5, line 6 column 6, line 36; claims 1-18) already discloses the subject-matter of claims 2-9,17-21,23-29,31. D2 (column 1, lines 3-5; column 2, lines 20-36; column 3, lines 14-33) already discloses the subject-matter of claims 2,3,6-12,17,18. D3 (column 2,

International application No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

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lines 41-50; column 3, lines 18-25; column 3, lines 59-65; column 8, lines 30-64; column 9, lines 8-17; column 9, lines 44-54) already discloses the subject-matter of claims 2-9. D4 (page 3, paragraph 31-39; page 4, paragraph 44-51) already discloses the subject-matter of claims 2,3,9-14,17-21. D5 (claims 1,5,8-11,17,18) already discloses the subject-matter of claims 2-4,6,9-12,17-19. D6 (pages 2,5-10) already discloses the subject-matter of claims 2-5,17,18. D7 (claims 1-9,13,21,22) already discloses the subject-matter of claims 2-7,9-12,17-20. D8 (column 4, lines 56-63; claims 1,3,4) already discloses the subject-matter of claims 2,4,6,9,10.